



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Roger P. Jackson

Serial No.: 10/767,646

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Filed: January 29, 2004

Group Art Unit: 3773

Docket No.: 10,390

Exam: Julian W. Woo

For: CLOSURE FOR OPEN HEADED MEDICAL IMPLANT

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Kansas City, Missouri

Appeal No. _____

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

ATTENTION: Board of Patent Appeals and Interferences

APPELLANT'S BRIEF

This brief is filed in support of the Notice of Appeal
in this application which was mailed on November 13, 2008.

The fees required under 41.2(b)(2) are submitted
herewith.

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I REAL PARTY IN INTEREST

The applicant Roger P. Jackson is the real party in interest.

II RELATED APPEALS AND INTERFERENCES

The following is a related patent application on appeal to the Board of Appeals:

Serial No. 10/142,614 which appeal has only recently been filed and with respect to which no Examiner's response has been received and to which no decision by the Board of Appeals has been entered.

III JURISDICTIONAL STATEMENT

This appeal is an appeal from a Patent Office action under 35 U.S.C. 134(a).

The Office action appealed from was mailed July 14, 2008. Several actions during the pendency of this application have been "Final" including the action of July 14, 2008.

The Notice of Appeal was filed November 13, 2008.

The Appeal Brief is being filed April 13, 2009 with a Request for Extension of Time for three months.

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V TABLE OF AUTHORITIES

Graham v. John Deere Co., 383 U.S. 1, 148 USPQ 459 (1966).

VI STATUS OF AMENDMENTS

There are no outstanding or pending amendments.

VII GROUNDS OF REJECTION TO BE REVIEWED

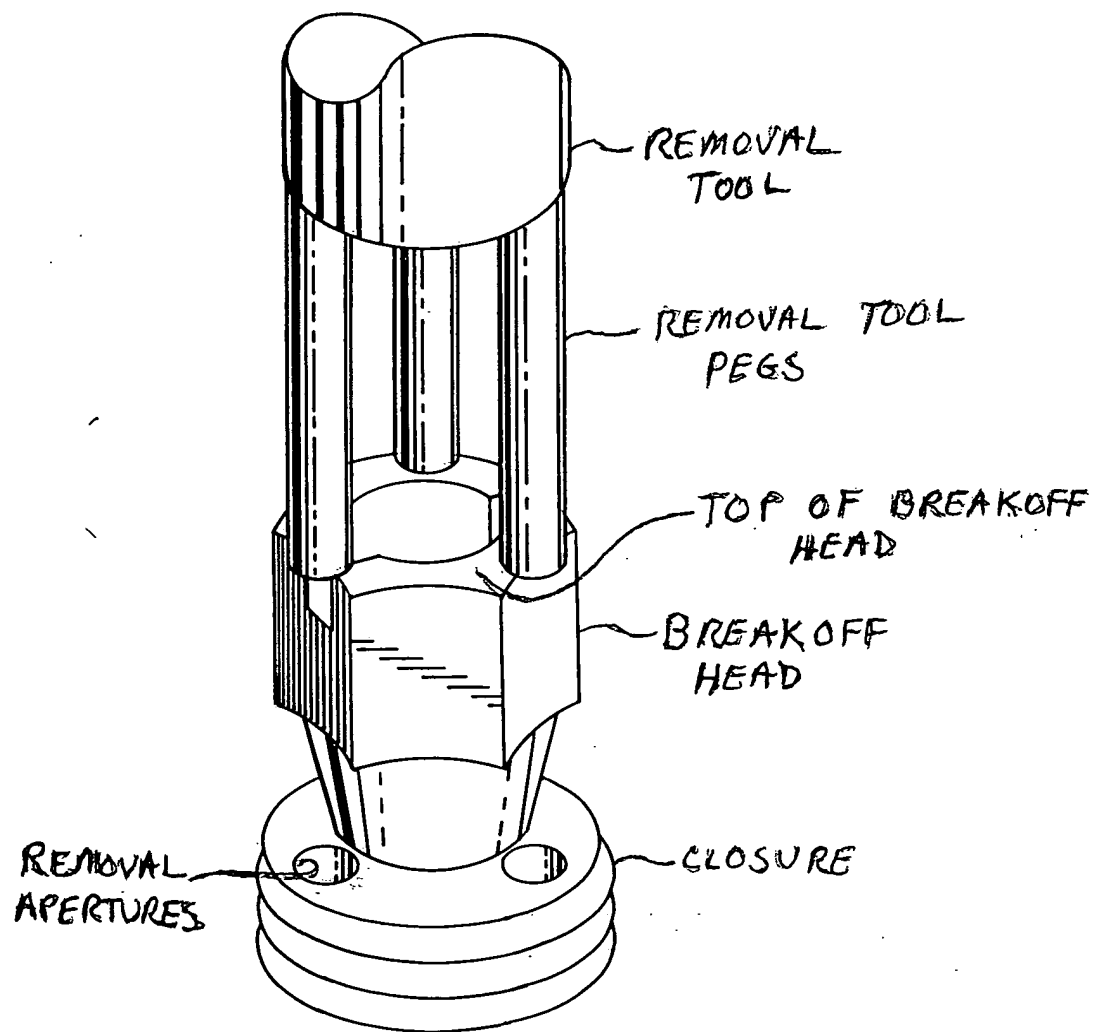
- 1) Is claim 14 properly rejected under 35 U.S.C. 102(b) as being anticipated by Dent (GB2140523A)?
- 2) Are Claims 1 to 3, 5, 6 and 13 properly rejected under 35 U.S.C. 103(a) as being unpatentable over Schilder (EP0276153) in view of Grunbichler (5,713,705) and further in view of Johnson (1,300,275)?
- 3) Is Claim 9 properly rejected under 35 U.S.C. 103(a) as being unpatentable over Schilder in view of Grunbichler and Johnson and further in view of Wagner (5,334,203)?
- 4) Is Claim 10 properly rejected under 35 U.S.C. 103(a) as being unpatentable over Schilder in view of Grunbichler and Johnson and further in view of Parker, et al. (6,053,078)?
- 5) Are Claims 7, 8, 11 and 12 properly rejected under 35 U.S.C. 103(a) as being unpatentable over Schilder in view of Grunbichler and Johnson and further in view of Reed (6,261,039)?

VIII STATEMENT OF FACTS

Open headed bone screw and hook implants have potentially splayable arms that receive a rod in a channel located between the arms in a channel generally defined by the arms. Thereafter, a closure is secured between the arms and over the rod to frictionally hold the rod in place relative to the screw or hook. If too much torque is applied to the closure the arms may bend or splay outward, thereby releasing the closure and allowing the implant to catastrophically fail. Break-off heads are provided to limit the torque to a range that will not splay the arms. That is, when a certain torque is reached the head breaks away with the intent to prevent overtorquing and normally prevent splaying of the arms.

Applicant is a spinal surgeon and has recognized that it is possible to circumvent the break-off head torque limiting structure, as provided for in the prior art. In particular, where structure, such as apertures in the body of the closure, is provided for removal of the closure, it is possible for the removal tool to be inadvertently or deliberately used to insert the closure. If this occurs and the removal tool can simultaneously engage the break-off head and the removal structure, then the closure can be overtorqued without the break-off head breaking away. Such a problem is seen in the cited prior art of Dent where there are pass through apertures drilled

through the break-off head and into the body (see especially apertures 20 in Figs. 9 and 14 of Dent). Because there is a direct and unobstructed path for the removal tool to follow down the apertures 20, it can engage both the break-off head and the apertures in the closure body simultaneously, possibly leading to the closure being over torqued and causing it to fail. Applicant resolves this problem by drilling the removal apertures (44, 45 and 46, see Fig. 8 of Jackson) from the bottom of the closure, such that the break-off head 36 overlaps and obstructs at least part of the apertures and prevents a surgeon from inserting a removal tool into the removal apertures until the break-off head is removed. The following is an illustration showing how applicant's closure blocks a removal tool.



In particular, the break-off head blocks the closure removal apertures until the head breaks away, so that when the head is in place (as in the above illustration), the removal pegs engage the

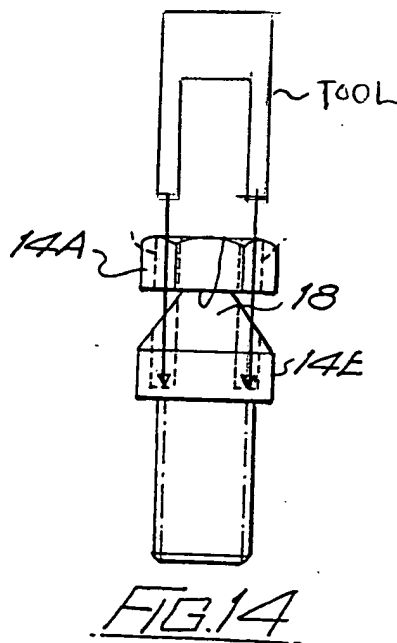
top of the head and cannot enter the removal apertures in the closure.

IX ARGUMENTS

1) Rejection of Claim 14 based on anticipation by Dent

Claim 14 calls for a closure having a break-off head and at least a pair of bores in the closure that are accessible from the top, but which are operably blocked from access by the break-off head when the head is in place.

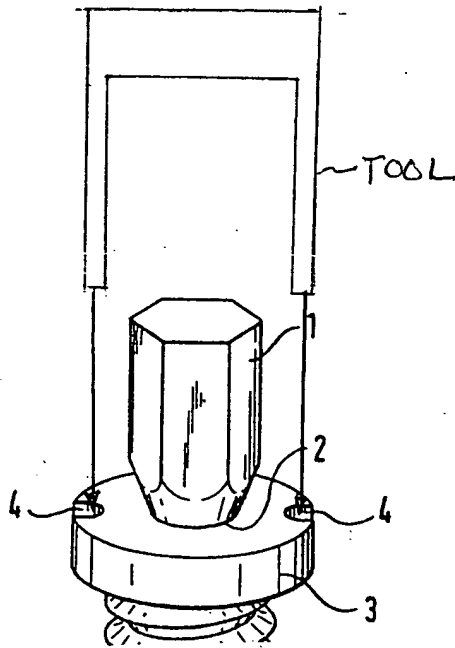
Figure 14 of the Dent reference is illustrated below, along with a tool and lines showing insertion added for illustration.



First, it is noted that Dent is not directed to a closure that is received between a pair of arms separated by a channel, but rather to a bolt or screw received in a fully surrounding bore. As can be seen from the drawings, the Dent device has sets of apertures that pass through both the head and the part of the body and both sets of apertures are axially aligned with one another. Consequently, a tool with pegs that can penetrate the break-off head apertures can inadvertently or deliberately be pushed at the same time into the apertures in the closure body. As previously noted, this can lead to overtorquing of a closure and consequent splaying of the arms in direct contradiction to the claim language and intent of the invention as called for in Claim 14. Therefore, it is urged that Claim 14 is not anticipated by Dent.

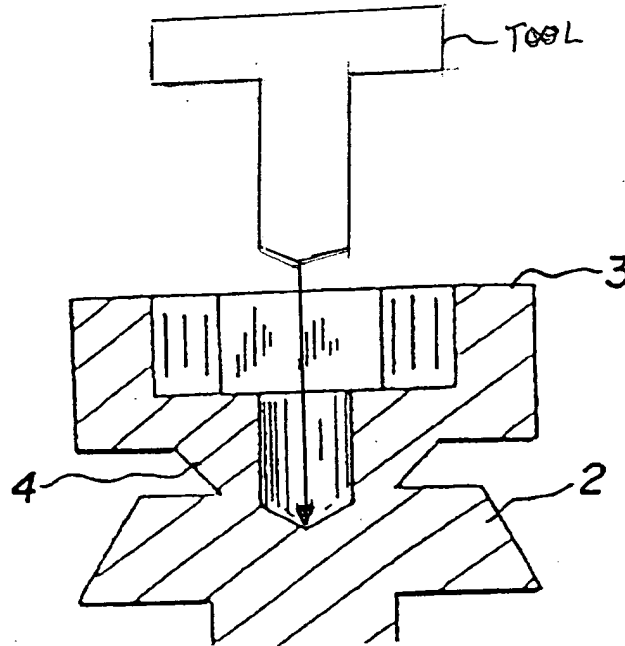
2) Rejection of Claims 1 to 3, 5, 6 and 13 as obvious over Schilder in view of Grunbichler and further in view of Johnson

Independent Claim 1 calls for a closure plug having a top surface with at least one bore to receive a removal tool and a break-off head wherein the break-off head is positioned to block access to any removal bore in the body until the break-off head is broken away. The following is Fig. 14 of Schilder shown in conjunction with a tool with a line added to show insertion.



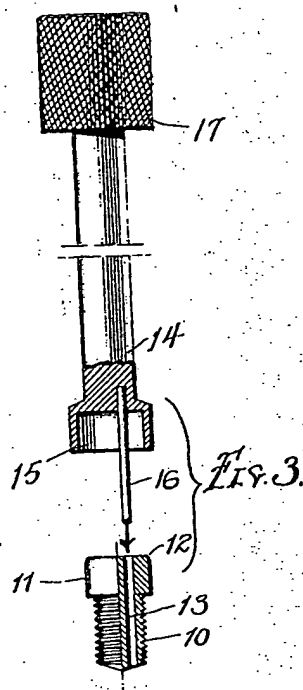
It is noted that Schilder is directed to a bone screw, not a closure. There is no pair of spaced arms that receive a closure between them. Furthermore, with the Schilder device there is always access for the removal tool to axially enter into the removal apertures. As shown in the illustration, a removal tool always can extend into the bores at the top of the bone screw, even when the break-off head is in place. In particular in Schilder, the removal bores are spaced radially outward from the break off head to allow access at all times.

The following figure is Fig. 9 of Grunbichler shown with a tool and an arrow added to show insertion.



It is also noted that Grunbichler is not directed to a closure for closing between spaced arms, but rather to a bolt that goes into a surrounding bore. Figures 1 and 9 of Grunbichler clearly show that this device has a central bore in the break-off head which allows axial access to the only aperture in the part of the bolt that remains after break off. The above figure shows how a tool would penetrate both the break-off head and the body at the same time.

Fig. 3 of Johnson is shown below.



Johnson is also not directed to a bone screw closure, but rather, a bolt that goes into a surrounding bore and a removal tool. The bolt has a non axial aperture in the top thereof. Johnson has no break off head and, as can be clearly seen in Figs. 1 to 5. The aperture in the top of the bolt is used for both insertion and removal and the aperture is always accessible by the tool.

Consequently, it is urged that none of Schilder, Grunbichler and Johnson are directed to a closure that goes between spaced arms and as such cannot address the problems of such a closure or how to resolve them. More importantly, in each of these cited references, the bore, apertures or openings on the top fo the bolt or other structure is always available for access by a tool and in none of the devices does a break-off head block access to the removal apertures or bores until the break-off head is removed. Consequently, it is urged that the cited references, whether taken singly or in combination fail to teach or suggest the claimed invention and that these claims are non obvious to one having ordinary skill in the art. It is urged that these claims are not obvious and are patentable under the standards set forth in Graham v. John Deere Co., 383 U.S. 1, 148 USPQ. 459 (1996).

3) Rejection of Claim 9 as obvious in view of a combination of
Schilder, Grunbichler, Johnson and Wagner

Claim 9 is dependent from Claim 1 and is urged to distinguish over all of the references, except Wagner for the same reasons as were discussed previously with respect to Claim 1. Wagner is cited for showing that the bores are spaced 120° apart. Wagner thus does not add anything to the other references with respect to showing elements of the Claim that are missing therein and also fails to show how such apertures would function with a break-off head or how to add a break-off head to cooperate with them. Consequently, it is urged that Claim 9 is also not made obvious by the art of the present rejection.

4) Rejection of Claim 10 as obvious in view of combination of
Schilder, Grunbichler, Johnson and Parker

Claim 10 depends from Claim 1 and is urged to overcome the cited references except for Parker for the same reasons as discussed for Claim 1. Parker is cited to show four bores and is urged to not show any of the elements that are missing from the other references that were discussed with respect to Claim 1. Consequently, it is urged that Claim 10 is not obvious to one having ordinary skill in the art in view of the cited references.

5) Rejection of Claims 7, 8, 11 and 12 as obvious in view of a
combination of Schilder, Grunbichler, Johnson and Reed

Claims 7, 8, 11 and 12 depend from Claim 1 and are urged to distinguish from the cited references, except for Reed for the same reasons as were discussed for Claim 1. Reed is cited as showing an axially extending bore from the bottom to a top of a structure. It is noted that Reed is not directed to a closure that goes between spaced arms. The device receives a bolt in an aperture that is always accessible. Consequently, it is urged that Reed does not provide, nor in any way suggest the elements missing from the other references that are called for in this group of claims. Consequently, it is urged that Claims 7, 8, 11 and 12 are also not obvious in view of the art of record.

In summary, it is urged that the cited references fail to anticipate, teach or suggest applicant's claimed inventions and that none of the pending claims are obvious to one having ordinary skill in the art in view of the references of record.

X CLAIMS APPENDIX

A. PENDING CLAIMS

Claim 1 A closure plug adapted for use with an open-headed medical implant having a pair of spaced and interiorly threaded arms; said plug comprising:

- a) a body sized and shaped to be threadedly received between and in the spaced arms of the implant head; said body having a radially outward surface that has a thread thereon that is sized and shaped to threadedly mate with the threaded arms of the implant;
- b) said body having a top surface and a bottom surface; said top surface of said body having at least one bore therein sized and shaped to receive a removal tool and extending generally axially entirely through said body from top to bottom thereof and opening onto said top surface; wherein:
- c) said bore is spaced from and positioned between both a central axis of said body and a periphery of said body; and
- d) a break-off head attached to said body at a neck and being breakable from said body at a preselected torque; said neck being axially aligned with said body; said break-off head being positioned so as to

be axially located above said body and at least a portion of said bore; said break-off head being free of pass through openings so as to block axial access by the removal tool to said bore until said break-off head breaks from said body.

Claim 2 The closure plug according to Claim 1 wherein:

- a) there are a pair of spaced bores extending into said body from the top surface thereof.

Claim 3 The closure plug according to Claim 1 wherein:

- a) said body is generally cylindrical in shape.

Claim 4 (Canceled)

Claim 5 The closure plug according to claim 1 wherein:

- a) said body includes at least a pair of said bores in the top thereof; and
- b) said neck is positioned between said bores.

Claim 6 The closure plug according to Claim 1 wherein:

- a) said break-off head has a tool grippable outer surface for operably rotating said closure during insertion into an implant and said neck being sized

and shaped such that said break-off head breaks from said body when a preselected torque is applied to said break-off head by such a gripping tool with a generally clean profile at said top surface.

Claim 7 The closure plug according to Claim 1 wherein:

- a) said closure includes an axial threaded bore passing entirely through said body from a top to a bottom thereof.

Claim 8 The closure plug according to Claim 7 in combination with:

- a) a threaded set screw sized and shaped to be received in said axial bore; said axial set screw being also sized and shaped to extend outward from said body bottom surface when said screw is fully installed therein.

Claim 9 The closure plug according to Claim 1 wherein:

- a) said body top surface has three spaced tool receiving bores located therein; each of said bores being located at a common radius from said body central axis and being spaced at 120° from adjacent

tool receiving bores.

Claim 10 The closure plug according to Claim 1 wherein:

- a) said body top has four spaced tool receiving bores each being located at a common radius from said body central axis and being evenly spaced from adjacent tool receiving bores.

Claim 11 The closure plug according to Claim 1 wherein:

- a) said body includes an axial extending bore from the bottom to near the top thereof; said axial bore being located beneath said neck and being accessible from a top of said body when said break-off head breaks away from said body.

Claim 12 The closure plug according to Claim 11 wherein:

- a) said axial bore is threaded.

Claim 13 The closure plug according to Claim 1 including:

- a) a tool having a grippable handle and an engagement face; said face including a post extending parallel to an axis of rotation of said tool for each said body bore; each said post being sized, aligned and

positional to simultaneously enter a respective bore so as to rotate and apply torque to said body when said tool is rotated about the axis thereof, whereby said tool is operable to at least remove said body from an implant in which said body has been inserted.

Claim 14 In a plug closure for operably closing a top of a channel between two arms of an open headed medical implant, the improvement comprising:

- a) said closure having at least a pair of bores each being positioned in spaced relationship to both an axis of said closure and to a periphery of said closure; said bores being parallel to said axis and being accessible from a top of said closure; and
- b) a break-off head attached to the top of said closure and operably blocking axial access to said bores such that a removal tool cannot be axially inserted into said bores when said break off head is attached to said closure; said break off head being breakable from the closure upon application of a preselected torque to said break-off head, when said closure is positioned between the arms, said break off head being free of openings

providing axial access to at least a portion of each of said bores such that said bores are positioned so as to be axially inaccessible by the removal tool until said break-off head is broken from said closure.

Claim 15 (Canceled)

B. CLAIM SUPPORT AND DRAWING ANALYSIS

Claim 1 A closure plug {6, page 9, line 11 to page 14, line 22 and see Figs. 1 to 8} adapted for use with an open-headed medical implant {5, page 9, line 11 to page 14, line 22} having a pair of spaced and interiorly threaded arms {21 and 22, page 9, line 21 to page 10, line 23}; said plug comprising:

- a) a body {35, page 10, line 11 to page 10, line 19} sized and shaped to be threadedly received between and in the spaced arms of the implant head {13, page 9, line 16 to page 10, line 1}; said body having a radially outward surface {40, page 10, lines 13-23} that has a thread {41, page 10, lines 19-23} thereon that is sized and shaped to threadedly mate with the threaded arms of the implant;
- b) said body having a top surface and a bottom surface {49 and 50, page 11, lines 4-7}; said top surface of said body having at least one bore {44, 45 and 46, page 11, lines 1-5} therein sized and shaped to receive a removal tool {78, page 13, line 17 to page 14, line 9} and extending generally axially entirely through said body from top to bottom thereof and opening onto said top surface {page 11, lines 5-7 and Fig. 8}; wherein:

- c) said bore is spaced from and positioned between both a central axis {A, page 10, lines 15-16} of said body and a periphery {48, page 11, line 4} of said body {page 11, lines 1-11}; and
- d) a break-off head {36, page 10, line 11 to page 13, line 9} attached to said body at a neck {54, page 11, lines 12 to 20} and being breakable from said body at a preselected torque {page 12, line 23 to page 13, line 4}; said neck being axially aligned with said body {page 11, lines 1 to 20 and Figs. 1 to 3}; said break-off head being positioned so as to be axially located above said body and at least a portion of said bore {page 11, line 12 to page 13 line 9, and especially Fig. 5}; said break-off head being free of pass through openings so as to block axial access by the removal tool to said bore until said break-off head breaks from said body {page 3, line 21 to page 4, line 7; page 10, line 11 to page 14, line 22 and especially as seen in Fig. 5}.

Claim 14 In a plug closure {6, page 9, line 11 to page 14, line 22 and see Figs. 1 to 8} for operably closing a top of a channel {23, page 9, line 21 to page 10, line 2} between two arms {21 and 22, page 9, line 21 to page 10, line 23}

of an open headed medical implant {1, page 9, lines 8-15, and Fig. 1}, the improvement comprising:

- a) said closure having at least a pair of bores {44, 45 and 46, page 9, line 23 to page 11, line 1, page 14, line 22, and Fig. 8} each being positioned in spaced relationship to both an axis of said closure and to a periphery of said closure; said bores being parallel to said axis and being accessible from a top of said closure {page 11, line 1 to page 14, line 9}; and
- b) a break-off head {36, page 10, line 11 to page 12, line 6} attached to the top {49, page 11, lines 12-15} of said closure and operably blocking axial access to said bores such that a removal tool {78, page 13, line 16 to page 14, line 22, and see Fig. 8} cannot be axially inserted into said bores when said break off head is attached to said closure; said break off head being breakable from the closure upon application of a preselected torque {page 12, line 23 to page 13, line 4} to said break-off head, when said closure is positioned between the arms, said break off head being free of openings providing axial access to at least a portion of each of said bores such that said bores

are positioned so as to be axially inaccessible by the removal tool until said break-off head is broken from said closure {page 3, line 21 to page 4, line 7; page 10, line 11 to page 14, line 19; and especially as seen in Fig. 5}.

C. EVIDENCE APPENDIX

NONE

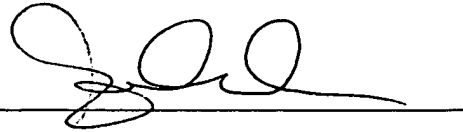
D. RELATED PROCEEDINGS APPENDIX

NONE

Respectfully submitted,

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Roger P. Jackson

By _____



April 13, 2009

(Date of Signature)